

Abstract

The Issue of Reimbursement and Price Regulation of Medicinal Products during Provision of Health Services

This master thesis deals with the price and reimbursement regulation of medicinal products in the Czech Republic and with selected problematic aspects of this field. The thesis describes and analyzes the issue in broader, especially economic, contexts and aims to give the reader a comprehensive view of the subject.

The work itself is divided into nine chapters. The introductory chapter outlines the issue of prices of medicinal products in general and outlines healthcare reforms that have attempted to focus more or less successfully on problematic aspects of the field.

The following chapter is devoted to explaining the terms that are key or somehow unclear to health or pharmaceutical law.

The third chapter deals with an economic approach to regulation and aims to explain to readers why regulation by state authorities in modern society is in some cases important and in some cases even necessary. There are also described and explained the tools of regulation and at the conclusion of the chapter the economic approach is directly reflected in the situation of the market of medicinal products in the territory of the Czech Republic.

The following chapter characterizes the actual entry of a particular medicinal product into the market. It therefore deals with the research of medicinal products, their registrations and analyzes the possibility of receiving a medicinal product, which has not obtained the necessary registration, to the patient.

The fifth chapter contains the key historical aspects concerning the price and reimbursement of medicines in the Czech Republic, which have shaped the current legal regulation of the whole issue. The influence of the Czech Republic's accession to the EU is described and also the case law of the Supreme Administrative Court of the Czech Republic and the Constitutional Court of the Czech Republic is analyzed, which explains why it was necessary to change the previous system and set it differently.

The sixth and seventh chapters deal with the pricing and reimbursement regulation of medicinal products, outlining the course of administrative procedures and explaining the principles that work in this field.

The eighth chapter deals with the issue of medicinal products that are not covered by standard public health insurance, so, they are within the system outside the regimes described in the previous two chapters. This group of medicinal products is very problematic, especially due to the considerable cost for the entire system of the Czech healthcare system. Recently, this is a very current issue, as evidenced by two judgments of the Municipal Court in Prague in 2018.

At the end of the thesis, the above-mentioned findings are summarized, including a reflection on possible systemic changes in the regulation of prices of medicinal products, which must undoubtedly be complex, not only legal but also economically and politically appropriate.

Key words: medicinal products, reimbursement regulation, price regulation